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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,491	09/05/2003	Dagmar Beyerlein	5618.P3653	8370

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EXAMINER

HUH, BENJAMIN

ART UNIT PAPER NUMBER

3767

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,491

Applicant(s)

BEYERLEIN, DAGMAR

Examiner

Benjamin Huh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

Applicant's arguments, filed 10/20/06, with respect to Sicurelli have been fully considered and are persuasive. The 103 rejection of Sicurelli has been withdrawn. The reason why the arguments were found to be persuasive were due to the fact that Sicurelli's needle was flexible and would not be able to *penetrate* the tissue as stated in the second to last line of claim 1.

Applicant's arguments with respect to claims 1-3 & 5-12 have been considered but are now moot in view of the new ground(s) of rejection.

The examiner would also like to note with respect to applicant's arguments concerning the prior art of record from Sicurelli that the current application only consists of apparatus claims and wherein the references are seen to be fully capable of performing the functional language listed. For further clarification, the examiner would like to point out that the sensor of Sicurelli is capable of measuring the pressure and therefore would measure the pressure changes, but the independent claim does not state what the pressure measurement assembly does with the information obtained of

the pressures until dependent claims 11-12 except that 3 different pressures are measured.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 & 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sicurelli et al (US Patent No. 6162202) in view of Hood et al (US Patent No. 5746713). The Sicurelli reference discloses a system in figure 9 comprising a needle 100 with a first opening and a second opening and a lumen extending therethrough and a pressure measurement assembly (500,550) connected to a proximal portion of the needle to measure a fluid pressure flowing through the needle, wherein the lumen is fully capable of allowing a fluid to be injected therethrough at a predetermined rate and wherein the pressure measurement assembly is fully capable of measuring changes in the fluid flow rate due to its size, shape, and ability to work in the environment such as when the fluid is dispensed at a constant rate, when the needle contacts tissue, and when the needle penetrates tissue. Now even though the Sicurelli reference does not explicitly disclose the reference to be able to penetrate tissue attention is directed to Hood. The Hood reference teaches an irrigation needle for penetrating tissue in figures 1-4 and abstract. Therefore, it would be obvious to one of ordinary skill in the art at the

time of the invention to utilize the teachings of Hood in the device of Sicurelli in order to provide a needle which is capable of penetrating tissue to introduce irrigation fluid into a desired surgical site. Now even though the Sicurelli reference does not explicitly disclose in figure 9 the needle 100 to have apertures attention is directed to Sicurelli, figures 2-5. Sicurelli teaches the use of apertures in the needle communicable with the lumen and located at a predetermined distance from the end. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the needle of Sicurelli to utilize the apertures in order to provide a means to administer fluid through the sides of the needle. Also with the modification of the needle having apertures in the side wherein the device would then also be capable of measuring the second pressure change when the needle penetrates said tissue and the aperture becomes occluded.

With respect to claims 2-3, wherein the Sicurelli reference discloses that the fluid pressure includes the pressure of a therapeutic agent using a pressure measurement assembly (500,550) and wherein the therapeutic agent can be a drug, see figure 9 and col. 4 lines 15-18, and wherein the assembly comprises a fluid pressure sensor 550.

With respect to claims 5-10, wherein it would be obvious to one of ordinary skill in the art at the time of the invention to change the area of the aperture, the distance from the front end, or the diameter of the needle in order to control the amount of flow and the location of outflow.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sicurelli et al (US Patent No. 6162202) in view of Hood et al (US Patent No. 5746713)

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as applied to claim 1 and further in view of Schiller et al (US Patent No. 6546787 B1). Now even though Sicurelli does not explicitly disclose the use of a computer processor and a visual feedback system or an audible feedback system attention is directed to Schiller et al. The Schiller reference teaches the use of a computer processor 85 and a visual or audible feedback system with respect to the pressure, see figure 1 and col. 9 lines 35-48. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sicurelli with the teachings of Schiller in order to have a constant visual/audio feedback system for constantly monitoring the pressure and a computer processor for calculating and outputting pressure information. Also, wherein the processor would be fully capable of determining the penetration depths of the needle due to it's ability to work in the environment and is coupled to the feedback systems.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER
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